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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 200113-0009]

RIN 0694-XC055

Impact of the Implementation of the Chemical Weapons Convention (CWC) on Legitimate Commercial Chemical, Biotechnology, and Pharmaceutical Activities Involving

“Schedule 1” Chemicals (including “Schedule 1” Chemicals produced as Intermediates)

During Calendar Year 2019

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of inquiry.

SUMMARY: The Bureau of Industry and Security (BIS) is seeking public comments on the impact that implementation of the Chemical Weapons Convention (CWC), through the Chemical Weapons Convention Implementation Act and the Chemical Weapons Convention Regulations (CWCR), has had on commercial activities involving “Schedule 1” chemicals during calendar year 2019. The purpose of this notice of inquiry is to collect information to assist BIS in its preparation of the annual certification to the Congress on whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms are harmed by such implementation. This certification is required under Condition 9 of Senate Resolution 75 (April 24, 1997), in which the Senate gave its advice and consent to the ratification of the CWC.

DATES: Comments must be received by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION].

ADDRESSES: You may submit comments by any of the following methods (please refer to RIN 0694-XC055 in all comments and in the subject line of e-mail comments):

- Federal rulemaking portal (<http://www.regulations.gov>) – you can find this notice by searching on its regulations.gov docket number, which is BIS-2019-0028;
- E-mail: willard.fisher@bis.doc.gov – include the phrase “Schedule 1 Notice of Inquiry” in the subject line;
- Fax: (202) 482-3355 (Attn: Willard Fisher);
- By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: For questions on the Chemical Weapons Convention requirements for “Schedule 1” chemicals, contact Douglas Brown, Treaty Compliance Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482-2163. For questions on the submission of comments, contact Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482-2440.

SUPPLEMENTARY INFORMATION:

Background

In providing its advice and consent to the ratification of the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and Their Destruction, commonly called the Chemical Weapons Convention (CWC or “the Convention”), the Senate included, in Senate Resolution 75 (S. Res. 75, April 24, 1997), several

conditions to its ratification. Condition 9, titled “Protection of Advanced Biotechnology,” calls for the President to certify to Congress on an annual basis that “the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are not being significantly harmed by the limitations of the Convention on access to, and production of, those chemicals and toxins listed in Schedule 1.” On July 8, 2004, President Bush, by Executive

Order 13346, delegated his authority to make the annual certification to the Secretary of Commerce.

The CWC is an international arms control treaty that contains certain verification provisions. In order to implement these verification provisions, the CWC established the Organization for the Prohibition of Chemical Weapons (OPCW). In order to achieve the object and purpose of the Convention and the implementation of its provisions, the CWC imposes certain obligations on countries that have ratified the Convention (i.e., States Parties), among which are the enactment of legislation to prohibit the production, storage, and use of chemical weapons and the establishment of a National Authority to serve as the national focal point for effective liaison with the OPCW and other States Parties. The CWC also requires each State Party to implement a comprehensive data declaration and inspection regime to provide transparency and to verify that both the public and private sectors of the State Party are not engaged in activities prohibited under the CWC.

“Schedule 1” chemicals consist of those toxic chemicals and precursors set forth in the CWC “Annex on Chemicals” and in “Supplement No. 1 to part 712 – SCHEDULE 1 CHEMICALS” of the Chemical Weapons Convention Regulations (CWCR) (15 CFR parts 710-

722). The CWC identified these toxic chemicals and precursors as posing a high risk to the object and purpose of the Convention.

The CWC (Part VI of the “Verification Annex”) restricts the production of “Schedule 1” chemicals for protective purposes to two facilities per State Party: a single small-scale facility (SSSF) and a facility for production in quantities not exceeding 10 kg per year. The CWC Article-by-Article Analysis submitted to the Senate in Treaty Doc. 103-21 defined the term “protective purposes” to mean “used for determining the adequacy of defense equipment and measures.” Consistent with this definition and as authorized by Presidential Decision Directive (PDD) 70 (December 17, 1999), which specifies agency and departmental responsibilities as part of the U.S. implementation of the CWC, the Department of Defense (DOD) was assigned the responsibility to operate these two facilities. DOD maintains strict controls on “Schedule 1” chemicals produced at its facilities in order to ensure accountability for such chemicals, as well as their proper use, consistent with the object and purpose of the Convention. Although this assignment of responsibility to DOD under PDD-70 effectively precluded commercial production of “Schedule 1” chemicals for “protective purposes” in the United States, it did not establish any limitations on “Schedule 1” chemical activities that are not prohibited by the CWC.

The provisions of the CWC that affect commercial activities involving “Schedule 1” chemicals are implemented in the CWCR (see 15 CFR part 712) and in the Export Administration Regulations (EAR) (see 15 CFR 742.18 and 15 CFR part 745), both of which are administered by the Bureau of Industry and Security (BIS). Pursuant to CWC requirements, the CWCR restrict commercial production of “Schedule 1” chemicals to research, medical, or pharmaceutical purposes. The CWCR prohibit commercial production of “Schedule 1”

chemicals for “protective purposes” because such production is effectively precluded per PDD-70, as described above. See 15 CFR 712.2(a).

The CWCR also contain other requirements and prohibitions that apply to “Schedule 1” chemicals and/or “Schedule 1” facilities. Specifically, the CWCR:

- (1) Prohibit the import of “Schedule 1” chemicals from States not Party to the Convention (15 CFR 712.2(b));
- (2) Require annual declarations by certain facilities engaged in the production of “Schedule 1” chemicals in excess of 100 grams aggregate per calendar year (i.e., declared “Schedule 1” facilities) for purposes not prohibited by the Convention (15 CFR 712.5(a)(1) and (a)(2));
- (3) Provide for government approval of “declared Schedule 1” facilities (15 CFR 712.5(f));
- (4) Provide that “declared Schedule 1” facilities are subject to initial and routine inspection by the OPCW (15 CFR 712.5(e) and 716.1(b)(1));
- (5) Require 200 days advance notification of the establishment of new “Schedule 1” production facilities producing greater than 100 grams aggregate of “Schedule 1” chemicals per calendar year (15 CFR 712.4);
- (6) Require advance notification and annual reporting of all imports and exports of “Schedule 1” chemicals to, or from, other States Parties to the Convention (15 CFR 712.6, 742.18(a)(1) and 745.1); and
- (7) Prohibit the export of “Schedule 1” chemicals to States not Party to the Convention (15 CFR 742.18(a)(1) and (b)(1)(ii)).

For purposes of the CWCR (see 15 CFR 710.1), “production of a Schedule 1 chemical” means the formation of “Schedule 1” chemicals through chemical synthesis, as well as processing to extract and isolate “Schedule 1” chemicals. The phrase “production of a schedule 1 chemical” includes, in its meaning, the formation of a chemical through chemical reaction, including by a biochemical or biologically mediated reaction. “Production of a Schedule 1 chemical” is understood, for CWCR declaration purposes, to include intermediates, by-products, or waste products that are produced and consumed within a defined chemical manufacturing sequence, where such intermediates, by-products, or waste products are chemically stable and therefore exist for a sufficient time to make isolation from the manufacturing stream possible, but where, under normal or design operating conditions, isolation does not occur.

Request for Comments

In order to assist in determining whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are significantly harmed by the limitations of the Convention on access to, and production of, “Schedule 1” chemicals as described in this notice, BIS is seeking public comments on any effects that implementation of the CWC, through the Chemical Weapons Convention Implementation Act and the CWCR, has had on commercial activities involving “Schedule 1” chemicals during calendar year 2019. To allow BIS to properly evaluate the significance of any harm to commercial activities involving “Schedule 1” chemicals, public comments submitted in response to this notice of inquiry should include both a quantitative and qualitative assessment of the impact of the CWC on such activities.

Submission of Comments

All comments must be submitted to one of the addresses indicated in this notice. The Department requires that all comments be submitted in written form. BIS will consider all comments received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. All comments, including those comments containing any personally identifying information or information for which a claim of confidentiality is asserted either in the comments or their transmittal e-mails, will be made available for public inspection and copying. Parties who wish to comment anonymously may do so by submitting their comments via Regulations.gov, leaving the fields that would identify the commenter blank and including no identifying information in the comment itself.

Richard E. Ashooh

Assistant Secretary

for Export Administration

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